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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,994	09/26/2001	Audrey Goddard	P3121R1	2989

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EXAMINER

KEMMERER, ELIZABETH

ART UNIT PAPER NUMBER

1646

DATE MAILED: 07/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/964,994

Applicant(s)

GODDARD ET AL.

Examiner

Elizabeth C. Kemmerer, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 12 May 2003.

2a) ☒ This action is **FINAL**.

2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 53-69 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 53-69 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.

4) ☐ Interview Summary (PTO-413) Paper No(s). _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The amendment filed 15 May 2003 (Paper No. 14) has been entered in full. Claims 1-52 are canceled. It is noted that the newly submitted claim following claim 63 was numbered "1". This claim has been renumbered under 37 CFR 1.126 as "64". Claims 53-69 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection of claims 4, 9, 10, 11, 12, 16 and 17 under 35 U.S.C. § 112, second paragraph, as set forth at pp. 3-4 of the previous Office Action (Paper No. 12, 17 January 2003) is *withdrawn* in view of the canceled and newly submitted claims (Paper No. 14, 12 May 2003).

35 U.S.C. § 112, Second Paragraph

Claims 53-57 and 66-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 53-57, there is improper antecedent basis for the phrase "said encoded polypeptide" appearing near the end of each claim. There are several polypeptides

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recited in various arts of the claims. For example, see claim 53, parts a and b. Other parts of the claim do not specifically recite an encoded polypeptide (for example, claim 53, parts c and d). The following is suggested: delete "said encoded polypeptide" and replace with "said isolated nucleic acid encodes a polypeptide which".

Claim 66 is indefinite because it depends from canceled claim 1.

35 U.S.C. § 101

Claims 53-69 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well-established utility. The basis for this rejection is set forth at pp. 4-7 of the previous Office Action (Paper No. 12, 17 January 2003).

Applicant's arguments (pp. 7-9, Paper No. 14, 12 May 2003) have been fully considered but are not deemed to be persuasive for the following reasons.

After reviewing the legal standard for utility, Applicant argues that the PRO19598 polypeptide encoded by the claimed polynucleotides specifically bind PRO3301 of SEQ ID NO: 4. Applicant argues that PRO3301 is over-expressed in certain cancers as compared to normal controls, as disclosed in Example 13. Applicant also refers to concurrently performed experiments in which it was found that PRO3301 was overexpressed in 3 cancerous tissues relative to normal control samples. Therefore, Applicant concludes that the PRO19598 encoded by the claimed polynucleotides have patentable utility at least in their being able to bind/label PRO3301 in cancer diagnostic assays. This has been fully considered but is not found to be persuasive. Regarding

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Example 13, it is not clear that the "universal normal control" is an appropriate control. The universal control is a combined sample of epithelial cells from several sources. If a gene is expressed in a tissue-specific manner in any one of these samples, its presence will be diluted in the control due to the presence of the other cells. Therefore, if a gene is expressed at a high level in a colon tumor sample, and the expression is lower in the universal control, it is not clear that the result indicates that the gene is a colon cancer marker, or if the normal, colon-specific expression of the gene was diluted in the universal control, thus making it appear to be present in a higher level in the colon tumor sample. If Applicant is aware of this type of control used in any other published work, Applicant is invited to submit copies of such publications as evidence that the universal normal control used in the specification is an art-accepted control. regarding the new experiments reported in the arguments, these results may be probative of the utility of the claimed invention. However, it is not appropriate to provide such new data as arguments. They must be provided in the form of a declaration under 37 CFR 1.132 or as published data, such that the data can be submitted properly as evidence which can be objectively interpreted by the examiner. The methodology and samples used, for example, must have been disclosed in the specification as originally filed, or known in the prior art. This cannot be determined from the results provided in the response.

For all of these reasons, the rejection is maintained.

Claims 53-69 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility for the reasons set forth

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above, one skilled in the art clearly would not know how to use the claimed invention.

The basis of this rejection is set forth at p. 7 of the previous Office Action (Paper No. 12, 17 January 2003).

Applicant argues (p. 9, Paper No. 14, 12 May 2003) that the rejection should be withdrawn for the same reasons provided in the traversal of the rejection under 35 U.S.C. § 101 for lack of utility. This has been fully considered but is not found to be persuasive for the same reasons given above in the maintained rejection under 35 U.S.C. § 101.

Claims 64-69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis of this rejection is the same as that set forth at pp. 7-9 of the previous Office Action (Paper No. 12, 17 January 2003).

Applicant argues (pp. 9-10, Paper No. 14, 12 May 2003) that the newly submitted claims recite structural and functional limitations for the encoded polypeptides, thereby overcoming the rejection under 35 U.S.C. § 112, first paragraph, regarding inadequate written description of a claimed genus. This has been fully considered and is persuasive for claims 53-63. However, claims 64-69 still recite a genus of polynucleotides, but no functional limitations.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D., whose telephone number is (703) 308-2673. The examiner can normally be reached on Mondays through Thursdays from 6:30 a.m. to 4:00 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ECK
June 30, 2003



ELIZABETH KEMMERER
PRIMARY EXAMINER